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January 3, 2003

Brian L. Strom, M.D., M.P.H., Chair
Committee on Smallpox Vaccination Program Implementation
c/o Institute of Medicine
500 Fifth Street, NW
Washington, DC 20001

Dear Dr. Strom:

With the first wave of smallpox vaccinations scheduled to begin later this month, your committee's work at the Institute of Medicine to advise the Centers for Disease Control and Prevention (CDC) on the implementation of this program could not be more important and timely.

I am writing to ask the committee to consider whether the informed consent process for the smallpox vaccine should disclose information about the ability of persons who are injured by the vaccine to obtain compensation for medical expenses, lost earnings, or disabilities. Without disclosure as part of the informed consent, many persons may erroneously assume that the existing federal program for compensating for vaccine-related injuries applies to the smallpox vaccine. Disclosure is also needed because provisions included in the recently enacted homeland security legislation (P.L. 107-269) limit the ability of anyone injured by the vaccine to obtain compensation. Without disclosure, few members of the public are likely to be well informed about the implications of these complex provisions.

As you know, the smallpox vaccine can cause rare but serious complications in those who are vaccinated and their close contacts. These adverse effects, which include progressive vaccinia, eczema vaccinatum, and encephalitis, can lead to profound disability and even death. Given these risks, a full understanding of the potential long-term consequences of a severe vaccine-related injury for an individual and his or her family are material to the vaccination decision. This should include a discussion of whether there is an opportunity for someone injured by the smallpox vaccine to obtain compensation.

The current vaccine information statements distributed with routine childhood vaccinations and often discussed with patients by clinicians during the informed consent process explicitly address the issue of compensation. The information specifically states: "In the rare event that you or your child has a serious reaction to a vaccine, there is a federal program that can help pay for the care of those who have been harmed."¹ The information statements then explain how to access this program.

In the case of the smallpox vaccine, however, this compensation program is not available. This creates a risk of significant misunderstandings. Unless the smallpox information statements expressly address the issue, many individuals are likely to assume that the existing federal compensation program for vaccines is also applicable to the smallpox vaccine. It is inconsistent with the goal of informed consent to address the issue of compensation in one circumstance (when the compensation is available) but not in the other (when the compensation is not available).

Moreover, the need for disclosure as part of informed consent is magnified by recent changes in federal law that directly affect the compensation issue. Under the recently passed homeland security legislation, there is little opportunity for someone injured by the smallpox vaccine to obtain compensation for an injury beyond existing insurance and workers compensation arrangements. Some of those vaccinated may not have access to any such protections, and those that do may find them inadequate to cover medical bills, replace lost income, or otherwise provide for their families. The homeland security law cut off other avenues of recompense for those injured by the vaccine by prohibiting them from suing vaccine manufacturers, hospitals, or doctors. Under the new law, vaccine recipients can only sue the federal government under the restrictive Federal Tort Claims Act, which will be difficult to do because it requires a showing of negligence. Unless there is disclosure as part of the informed consent process, it is highly unlikely that persons who are considering whether to take the vaccine will be informed about their rights after these recent and complicated changes.

I am hopeful that the law regarding compensation for smallpox injuries will be revised by Congress. I and other members of Congress are developing legislation to establish a smallpox vaccine injury compensation program modeled on the successful childhood Vaccine Injury Compensation Program. Such a program would provide a "no fault" mechanism to compensate those injured directly or indirectly by the smallpox vaccine and would serve as a safety net for those vaccinated and their close contacts in case of injury. But whether we are successful or not, it is important that those taking the vaccine be accurately informed about relevant compensation issues at the time they are deciding whether to take the vaccine.

¹See, e.g. CDC, *Polio Vaccine: What You Need to Know* (January 2000).

Brian L. Strom, M.D., M.P.H., Chair

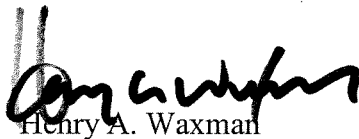
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The issues raised in this letter relate directly to one of the central charges of your committee, which is to make recommendations to improve "the informed consent process for vaccine recipients." Vaccine compensation issues may also be relevant to other objectives of your committee, including providing advice to CDC on "professional education and training materials," "communication plans developed by CDC for public health and medical professionals and the public," and "the achievement of overall goals of the smallpox vaccination program." I urge you to consider this important issue fully.

Thank you for considering my perspective on this subject. Please contact Sarah Despres or Joshua Sharfstein on my staff on the Government Reform Committee at 202-225-5420 if I can provide you with any additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Henry A. Waxman".

Henry A. Waxman
Ranking Minority Member